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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,292	05/31/2007	Chawnshang Chang	24376.18.8402	1600

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

NOTIFICATION DATE	DELIVERY MODE
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11/26/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

agg.patent.docketing@agg.com

Office Action Summary	Application No. 10/582,292	Applicant(s) CHANG, CHAWNSHANG	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 6-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on October 8, 2010 has been entered.

2. Claims 1-53 are pending.

Claims 6-53, drawn to non-elected inventions is withdrawn from examination.

Claim 1 has been amended.

Claim 53 has been added and is a non-elected invention. This claim reads on assaying for the presence of androgen independent androgen receptor activity, which requires a distinct and different assay and reagents.

Claims 1-5 are examined on the merits to the extent an antibody is used to detect the androgen receptor.

Withdrawn Grounds of Objections

Claim Objections

3. Claim 1 is no longer objected to because the conjunction, "and" has been deleted from line 2 and placed on line 4 between the recitations, "cancer," and "c) identifying", see newly submitted claim set, October 8, 2010.

Withdrawn Grounds of Rejection

Claim Rejections - 35 USC § 112

4. The ***NEW MATTER REJECTION*** of claims 1-5 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicant's arguments and statement of where support can be found in their specification, see Remarks submitted October 8, 2010, page 8.

Maintained Rejections

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. The rejection of claims 1-5 under 35 U.S.C. 102(e) as being anticipated by Thompson/ U.S. Patent number 7,029,859 B2 (filed March 5, 2001) is maintained.

Applicant sets forth the criteria for establishing a proper rejection under 102(e) and the corresponding sections of the MPEP, see Remarks submitted October 8, 2010, page 9. Applicant asserts Thompson teaches treatment of metastatic cancers through suppressing expression of the caveolin gene, see Remarks submitted October 8, 2010, page 8, last paragraph. Applicant further notes Example 2 mentions “androgen receptor” in relation to castration-induced

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regression of mouse prostate cancer. Applicant states the castration mouse model does not have anything to do with breast cancer or breast tissue.

Applicant's arguments and points of view have been carefully considered, but found unpersuasive.

Applicant is reminded again as noted in the Final Rejection mailed June 10, 2010 on page 4 their claims do not limit the tissue sample from any particular source. Hence, arguments directed to the prior art not reading on assaying a breast tissue sample are moot, see page 8, last paragraph of Remarks. The prior art continues to read on the two active method steps, obtaining a tissue sample and assaying for the presence of the androgen receptor. The identifying step seems to be a mental step completed once the said steps are conducted and simply expresses the intended result of the positively recited process steps. Applicant intimates the Examiner's rationale is illogical, however according to Applicant's own claims assaying any tissue for androgen receptor provides information regarding the receptor status and risk status, see last sentence on page 8 of Remarks.

Thompson discloses assessing androgen (AR) levels using a monoclonal antibody in tissues from both rodent and human model systems, see columns 22 and 23; and Figure 2. The tissue sample is not identified in the claims, hence can be from any source. Tissues from male subjects were analyzed for androgen levels (AR) using a monoclonal antibody, see lines 51-65; paragraph bridging columns 22 and 23; and Figure 2. Thompson's disclosure of caveolin

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does not preclude the instant rejection. Consequently, Thompson continues to anticipate the claims and is reiterated below.

7. The rejection of claims 1, 2, 4 and 5 under 35 U.S.C. 102(b) as being anticipated by Fujimoto et al. (Laboratory Investigation 80(9): 1465-1471, September 2000) is maintained.

Applicant aver while Fujimoto discloses “[a] tissue sample is obtained and androgen receptor is assayed...”, Fujimoto discloses EMPD and not breast cancer, see Remarks, page 12. Applicant further argues there is no correlation between the androgen receptor and increased risk of breast cancer, see Remarks, page 12. Applicant's arguments and points of view have been carefully considered, but found unpersuasive.

As stated previously in the 102(e) rejection the claimed invention reads on comprising two active steps, obtaining a tissue sample and assaying for the presence of the androgen receptor. Applicant is reminded again as noted in the Final Rejection mailed June 10, 2010 their claims do not limit the tissue sample from any particular source. Hence, arguments directed to the prior art not reading on assaying a breast tissue sample are moot. The prior art continues to read on the two active method steps, obtaining a tissue sample and assaying for the presence of the androgen receptor. The identifying step seems to be a mental step completed once the said steps are conducted and simply expresses the intended result of the positively recited process steps.

Applicant has submitted that Fujimoto reads on both limitations, see page 12 of Remarks; and Fujimoto, page 1469, Materials and Methods section. The correlation set forth in Applicant's claim 1 is still established in Fujimoto based on it reading on the two limitations or steps in the claim. Consequently, Fujimoto anticipates the claim and the rejection is maintained.

8. The rejection of claims 1, 2 and 4 under 35 U.S.C. 102(a) as being anticipated by Moinfar et al. (Cancer 98(4): 703-711, August 15, 2003) is maintained.

Applicant avers the "Moinfar... [does] *not* describe a correlation between [the] androgen receptor and the increased risk or presence of breast cancer, see Remarks, page 13, 2nd paragraph. As the claims are written there are two active steps, obtaining a tissue sample and assaying for the presence of the androgen receptor. Applicant is reminded again as noted in the Final Rejection mailed June 10, 2010 their claims do not limit the tissue sample from any particular source. Hence, arguments directed to the prior art not reading on assaying a breast tissue sample are moot. Moreover, Moinfar analyzing ER, PR, and Her2/neu does not preclude the fact Moinfar reads on the claims. The prior art continues to read on the two active method steps, obtaining a tissue sample and assaying for the presence of the androgen receptor. The identifying step seems to be a mental step completed once the said steps are conducted and simply expresses the intended result of the positively recited

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process steps. Applicant's arguments and points of view have been carefully considered, but found unpersuasive.

As set forth by Applicant in their Remarks and of record in the first action on the merits (FAOM) mailed September 3, 2009, Moinfar discloses immunohistochemical assays for AR in samples of breast carcinomas with antibodies, see page 704, Materials and Methods section. Moinfar's disclosure is regarded by the Examiner as meeting the limitations of the claims. The correlation set forth in Applicant's claim 1, step c) is established by Moinfar because the document reads on the two limitations or steps in the claim as a) and b). Consequently, Moinfar anticipates the claim and the rejection is maintained.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over Fujimoto et al. (Laboratory Investigation 80(9): 1465-1471, September 2000), and further in view of Thompson/ U.S. Patent number 7,029,859 B2 (filed March 5, 2001) is maintained.

Applicant sets forth the criteria for establishing a proper rejection under 103(a) and making a *prima facie* case of obviousness, see Remarks submitted October 8, 2010, pages 14-19. Applicant's arguments are based on the primary reference, Fujimoto does not teach the claimed invention. Applicant's arguments and points of view have been carefully considered, but found unpersuasive.

As noted earlier the anticipatory rejection under 102(b) is maintained and consequently the instant rejection is maintained.

11. The rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over Moinfar et al. (Cancer 98(4): 703-711, August 15, 2003), and further in view of Thompson/ U.S. Patent number 7,029,859 B2 (filed March 5, 2001) is maintained.

Applicant sets forth the criteria for establishing a proper rejection under 103(a) and making a *prima facie* case of obviousness, see Remarks submitted March 3, 2010, pages 15 and 19-21. Applicant's arguments are based on the primary reference, Moinfar does not teach the claimed invention. Applicant's arguments and points of view have been carefully considered, but found unpersuasive.

As noted earlier the anticipatory rejection under 102(a) is maintained and consequently the instant rejection is maintained.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached Monday through Saturday, 8 am to 8 pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Misook Yu, Ph.D. can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643